Docket No.: 071971-0366 **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	Customer Number: 53080
Yuko TANIIKE, et al.	:	Confirmation Number: 7373
Application No.: 10/550,150	:	Group Art Unit: 4112
Filed: September 21, 2005	:	Examiner: ANITA B. DAMRON

For: BIOSENSOR, AND BIOSENSOR MEASURING DEVICE AND METHOD

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Transmitted herewith is an Amendment in the above-identified application.

☒ No additional fee is required.
☐ Applicant is entitled to small entity status under 37 CFR 1.27
☐ Also attached:

The fee has been calculated as shown below:

	NO. OF CLAIMS	HIGHEST PREVIOUSLY PAID FOR	EXTRA CLAIMS	RATE	FEE
Total Claims	10	20	0	$52.00 =	$0.00
Independent Claims	1	3	0	$220.00 =	$0.00
		Multiple dependent claims newly presented			$0.00
		Fee for extension of time			$0.00
				Total of Above Calculations	$0.00

☐ Please charge my Deposit Account No. 500417 in the amount of $0.00. An additional copy of this transmittal sheet is submitted herewith.

☒ The Commissioner is hereby authorized to charge payment of any fees associated with this communication or credit any overpayment, to Deposit Account No. 500417, including any filing fees under 37 CFR 1.16 for presentation of extra claims and any patent application processing fees under 37 CFR 1.17.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

Michael E. Fogarty
Registration No. 36,139

Please recognize our Customer No. 53080 as our correspondence address.

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Date: November 12, 2008

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For: BIOSENSOR, AND BIOSENSOR MEASURING DEVICE AND METHOD

AMENDMENT

Mail Stop – Amendment
Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated August 11, 2008 having a shortened statutory period of response set to expire on November 11, 2008, please amend the above-identified application as follows:

IN THE CLAIMS:

Please amend the claims as follows:

1-11. (Cancelled)

12. (Currently amended) A measurement method for measuring a test substance included in a sample by using a biosensor, packed in a package, said biosensor including a substrate; a sample receiving section provided on said substrate and containing a reagent section including a reagent to be reacted with said test substance; and a moisture absorbing material changed in color through absorption of moisture, comprising the steps of:

removing said biosensor from said package;

~~fitting said biosensor on a biosensor measuring apparatus;~~

determining a degree of degradation of said reagent on the basis of a degree of color change of said moisture absorbing material; and

measuring said test substance under measurement when the degree of degradation of said reagent is determined to be small in the determining step and stopping to measure said test substance under measurement when the degree of degradation of said reagent is determined to be large.

13. (New) The biosensor of Claim 12, further comprising a cover for covering said moisture absorbing material,

wherein a part of said moisture absorbing material is exposed.

14. (New) The biosensor of Claim 13, wherein the degree of degradation of said reagent is shown on the basis of a degree of color change of a portion of said moisture absorbing material that is present at a given distance from the exposed part and is covered with said cover.

15. (New) The biosensor of Claim 12, wherein said reagent includes an enzyme.

16. (New) The biosensor of Claim 15, wherein said reagent section further includes an electron mediator.

17. (New) The biosensor of Claim 16, further comprising:

a pair of terminals provided on said substrate; and

a pair of electrodes provided in said sample receiving section to be spaced from each other and respectively connected to said pair of terminals.

18. (New) The biosensor of Claim 12, wherein said reagent includes at least one of an antibody and an antigen.

19. (New) The biosensor of Claim 12, wherein said moisture absorbing material is in the shape of a sheet.

20. (New) The biosensor of Claim 12, further comprising a covering member made of a light blocking material and formed over said substrate for covering said sample receiving section.

21. (New) The biosensor of Claim 19,

wherein said moisture absorbing material in the shape of a sheet is provided on a face of said substrate opposite to a face thereof on which said sample receiving section is provided, and

a sheet for covering said moisture absorbing material is provided on said moisture absorbing material.

REMARKS

I. Introduction

In response to the pending Office Action, Applicants have cancelled claims 1-11, without prejudice, amended claim 12 so as to more specifically recite the intended subject matter of the present disclosure, and have added new claims 13-21. Claims 13-21 correspond to original claims 2-10, respectively, but rewritten to depend on claim 12. No new matter has been added.

It is further noted that in the IDS filed concurrently with the Application, references JP 58-199020, JP 2002-014072 and JP 2003-302314 were indicated as crossed-out on the PTO-1449 form returned to the Applicants. As noted in the initial filing, these references were cited in the PCT search report and copies thereof should have been provided by the appropriate search authority. Applicants submit copies of these references concurrently with this response along with another PTO-1449. It is respectfully requested that these references be considered. If any fee is necessary to have such references considered at this time, Examiner is hereby authorized to charge the required fee to the deposit account identified below.

For the reasons set forth below, it is respectfully submitted that all pending claims are patentable over the cited prior art references.

II. The Rejection Of The Claims Under 35 U.S.C. § 103

Claim 12 was rejected under 35 U.S.C. § 103 as being unpatentable over USP No. 5,266,179 to Nankai in view of USP No. 5,843,691 to Douglas. Applicants respectfully submit that claim 12, and the claims dependent thereon, are patentable over Nankai and Douglas taken alone or in combination with one another for at least the reasons set forth below.

As recited by amended claim 12, the method of the present disclosure relates to a method of determining whether or not a biosensor is still effective for performing the intended testing for which it is utilized. In accordance with one of the main aspects of the present disclosure is that the biosensor includes a moisture absorbing material that changes in color when exposed, for example, to air. Referring to the exemplary embodiment of Fig. 1, the moisture absorbing material is element 16, which is disposed in recess 17 and covered with a film 18. As result of the structure of the device and the inclusion of the moisture absorbing material, it is possible for the user to determine, based on the color of the moisture absorbing material, whether or not the device is still effective for its intended purpose. As is known, exposing the biosensor to air can affect the reaction of enzyme or the electron mediator, thereby reducing the effectiveness and accuracy of the results. By including the color changing moisture absorbing material it is possible for the user to determine if a device already taken out of the package can still provide acceptable test results.

Turning to the cited prior art references and the pending rejection, it is clear that the neither of the prior art references, taken alone or in combination with one another, anticipate the pending claims. Douglas does not disclose any moisture absorbing material corresponding to the material utilized in the Applicants' device, which is separate and distinct from the reagent material. Douglas discloses a device in which the testing reagent undergoes a color change in response to the fluid sample being applied to the reagent strip. However, importantly, Douglas does not disclose or suggest any color changing moisture absorbing material, which is distinct and separate from the reagent material, and which changes color based on exposure to the moisture in air. Indeed, it would appear Douglas teaches the exact opposite as Douglas states that "[i]n the dry state, the reagent chemistry is not activated by the glucose" and goes on to state

that the sample must be applied. Furthermore, nowhere does Douglas appear to be concerned with providing an indication of the effectiveness of the device (i.e., degradation of the reagent).

Nankai also fails to disclose or suggest any moisture absorbing material corresponding to the material utilized in the Applicants' device, which is separate and distinct from the reagent material and which changes color. Nor is Nankai related to or concerned with solving the problem of determining how long the biosensor has been removed from the package so as to allow the user to readily determine if the biosensor is still capable of generating an accurate measurement. In contrast, Nankai provides a device which allows for determination of whether or not a chip mounted to the device is a sensor for measuring the sample or is an adjustment chip (*see*, claim 1 of Nankai). Nankai is unrelated to the method of the present disclosure or the problem solved thereby.

Thus, even assuming *arguendo* that the combination of Nankai and Douglas was proper, the combination still fails to disclose or suggest all of the limitations recited by pending claim 12, for at least the reasons set forth above. Nor is there any suggestion in either of these references that would lead one of skill in the art to modify the references so as to arrive at the method recited by claim 12 absent reference to Applicants' specification, as neither reference even acknowledges the problems identified and solved by the present disclosure.

Accordingly, as each and every element of the pending claims must be disclosed or suggested by the prior art references in order to establish a *prima facie* case of obviousness (*see*, M.P.E.P. §2143.03), and the combination of Nankai and Douglas clearly fails to do so for at least the reasons set forth above, it is submitted that claim 12 and the claims dependent thereon are patentable over Nankai and Douglas.

III. Dependent Claims

Under Federal Circuit guidelines, a dependent claim is nonobvious if the independent claim upon which it depends is allowable because all the limitations of the independent claim are contained in the dependent claims, *Hartness International Inc. v. Simplimatic Engineering Co.*, 819 F.2d at 1100, 1108 (Fed. Cir. 1987). Accordingly, as claim 12 is patentable for the reasons set forth above, it is respectfully submitted that all claims dependent thereon are also patentable. In addition, it is respectfully submitted that the dependent claims are patentable based on their own merits by adding novel and non-obvious features to the combination.

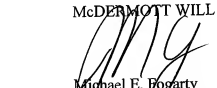
IV. Conclusion

Having fully responded to all matters raised in the Office Action, Applicants submit that all claims are in condition for allowance, an indication for which is respectfully solicited. If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, the Examiner is requested to call Applicants' attorney at the telephone number shown below.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



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